Author’s response to reviews

Title: A randomised controlled trial of performance review and facilitated feedback to increase implementation of healthy eating and physical activity-promoting policies and practices in centre-based childcare

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Author’s response to reviews:

Reviewer #1

Some minor points to highlight:

1. I am confused by the use of the term 'cluster randomised' in the title (p1). This is not used elsewhere in the article, nor indeed in the protocol. Given the unit of analysis is childcare centres, not individual children attending those centres, I would suggest removing the term.

Response: Thank you for drawing our attention to this. We agree and have now removed the term. The title now reads:

“A randomised controlled trial of performance review and facilitated feedback to increase implementation of healthy eating and physical activity-promoting policies and practices in centre-based childcare”
2. For the international reader, please could you provide a bit more information about what you mean by 'centre based childcare' - in the UK, I think we would call this a nursery (p3)?

Response: Thank you for this comment. In response we have added text outlining additional terms used to describe the setting. The new wording added to the relevant sentence on page 3 is underlined below:

“…centre-based childcare services (including organised group pre-school early education programs, infant classes, reception classes, nurseries, and day care centres)…..”

3. Linked to this, it would be useful to have a little more detail on how you identified the 366 centres eligible for inclusion, particularly as I think government-run centres were excluded (p6).

Response: In response we have included additional information describing how services in the sample were identified. The revised sentence on page 6 now reads:

“A list of all 366 childcare services in the region provided by the Early Childhood Education and Care Directorate (the Government Licensing Authority) served as the sampling frame.”

4. Could you also explain the role of Hunter New England Population Health (p6)? Are they a government body?

Response: Thank you for this comment. We have reworded the sentence adding information on the funding source and providing a better description of the role of Hunter New England Population Health. The sentence on page 6 now reads:

“This implementation trial was conducted as part of government funded health promotion services routinely delivered to all childcare services by a regional population health unit (Hunter New England Population Health (HNEPH)).”
5. In the section on implementation intervention (p7), it would be helpful if you could include a clear sentence which outlines what the intervention is. As you were seeking to implement and evaluate an intervention that in turn seeks to augment the implementation of public health policies, this reader got a bit confused on first reading!

Response: Thank you for drawing our attention to this. We agree that the structure as submitted was confusing. In response we have made changes to the wording and ordering of text within the methods sections on pages 7 and 8 and in the title. First, we have removed the term “intervention” from the title. Second, in the methods, we have replaced the term “intervention” with implementation strategy. Third, we have included two new subheadings under this broader heading which separate out the text describing the targeted policies and practices that were subject to implementation distinct from the “strategies” to support their implementation. Finally, we have moved the text describing application of Damschroder’s Consolidated Framework for Implementation Research describing development of content of the implementation strategy to the top of the section under the new “strategies” sub heading. We feel that separating out the text to describe targeted policies and practices and keeping all detail related to the implementation strategies and their content will reduce confusion experienced from the previous structure and wording.

Relevant text across pages 7 and 8 now reads:

“Implementation strategy” (amended heading)*

Policies and practices targeted for implementation (new sub-heading)*

We sought to increase service implementation of healthy eating and physical activity policies and practices consistent with best practice Australian healthy eating and physical activity guidelines for the childcare setting [12], and evidence reviews of policies and practices shown to be associated with child healthy eating and physical activity [20,33]. The policies and practices targeted for implementation included:

1. Service having written nutrition, physical activity and small screen recreation policies.
2. Service providing information to families (healthy eating, physical activity, small screen time and breast feeding, where relevant)

3. Service providing structured and specific learning experiences about healthy eating at least two times per week

4. Service supplying age appropriate drinks to children (only water and age-appropriate milk)

5. Service conducting fundamental movement skills activities for children aged 3-5 years every day to at least 90% of children

6. Service limiting use of small screen recreation by children aged 3-5 years to only educational purposes and for learning experiences”

The policies and practices were identified and targeted from a broader group of 15 practices for which Hunter New England Population Health was responsible for supporting childcare services to implement as part of a State-wide childhood obesity prevention initiative (Healthy Children Initiative). Policies and practices in this intervention were selected on the basis of existing health service monitoring data summarising policy and practice implementation by childcare services in the region [34]. The sub-group of targeted practices were included as they were those identified to have low prevalence of implementation.
Strategies (new sub-heading)*

The implementation intervention was primarily delivered to nominated supervisors of each childcare service via five cycles of performance review and facilitated feedback conducted over a period of 10 months. Formative work including consultations with local childcare services was conducted to identify relevant factors that may impede local implementation of the targeted policies and practices. Damschroder’s Consolidated Framework for Implementation Research (CFIR) was then used to help classify barriers and inform strategy content [35]. Damschroder’s Consolidated Framework for Implementation Research integrates 19 theoretical models and is composed of five major domains identified as influential in successful implementation: innovation characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Table 1 provides a summary of the four targeted constructs and how these were applied.

*bracketed terms not included in revised manuscript

6. In the outcomes section of the methods (p11), you mention that 12 items were used to assess the implementation of the policies. However, only 6 are listed?

Response: Thank you for this comment. For some policies and practices multiple survey items were used to assess their implementation. As currently worded we acknowledge that this is misleading to the reader. To address this we have indicated the number of survey items used to assess implementation for each listed policy and practice, prior to the text outlining the wording of these items.

Relevant additions to the text across pages 11/12 are underlined in the excerpt below:

1. Services having written nutrition, physical activity, and small screen recreation policies (three items) (all three, (which may be combined with another policy) (yes/no to having all three).
2. Service providing information to families on healthy eating, physical activity, small screen time, and breast feeding, where relevant (four items) (all topics). Information was required to be distributed at least once in the last 12 months and could include material handed directly to parents, mailed or emailed or placed in their child’s pigeon hole or bag, or information included in newsletters or at orientation (yes/no to all topics). Examples could include a list of recommended foods for lunchboxes and lunchbox ideas, physical activity and screen time recommendations for children, and breastfeeding guidelines.

3. Service providing structured and specific learning experiences about healthy eating at least two times per week (one item, yes/no). Examples included experiential activities about food, cooking skills, food growing (eg kitchen/vegetable gardens, planting seeds), tasting sessions, discussion around “everyday” and “sometimes” foods.

4. Service only supplying age-appropriate drinks to children including water and reduced fat plain milk (one item) (yes/no). For children less than 2 year olds the service reported supplying plain full fat milk.

5. Service conducting fundamental movement skills activities for children aged 3-5 years every day to at least 90% of children (two items). Where service reports the average number of days per week that educators lead structured activities to develop Fundamental Movement Skills (could be during transition activity, group or circle time or during outdoor play) is equal to all service opening days, and where service estimate of the percent of children that usually participate is 90 percent or greater (or are encouraged to participate if special needs).

6. Service limiting use of small screen recreation (one item) (i.e. TVs, videos, DVD, computers and other electronic games, iPads/tablets) by children aged 3-5 years to only educational purposes and for learning experiences such as to gain knowledge or share information about a specific learning area or child’s interest or to facilitate exploration of activity, dance or movement (yes/no).
Reviewer #2

The manuscript is well-written and describes the study clearly. I'm not sure I would have classified the implementation strategy as audit and feedback though. To me, the strategy described sounded more like facilitation to help the daycare centers to implement the desired interventions. Regardless of what you call it, I do think there was a facilitation piece going on in addition to the A&F from how you described the activities of the implementation support staff. It may be worthwhile to indicate this in the manuscript.

Response: Thank you for drawing our attention to this. We agree and have now added additional text on pages 8 and 9, referring to facilitation as part of the feedback process. We have also amended description of the strategy to include “facilitation”, which is reflected throughout the manuscript and in the title.

The title now reads:

“A randomised controlled trial of performance review and facilitated feedback to increase implementation of healthy eating and physical activity-promoting policies and practices in centre-based childcare”

Relevant text under the heading “Implementation strategies” now page 8 reads:

“The implementation intervention was primarily delivered to nominated supervisors of each childcare service via five cycles of performance review and facilitated feedback conducted over a period of 10 months.”

Page 9 reads:

“Facilitated feedback included a discussion of current implementation status, assessed on the basis of information reported by the nominated supervisor using standard criteria with support tailored to meet service needs based on the policies and practices not being implemented.”
Reviewer #3

Comments and questions for the authors are below. Although none of these should require major revisions, it would be helpful for the authors to address and revise their manuscript accordingly.

1. The authors describe the study as a pragmatic trial, both in the title and briefly in text. However, it is not clear that this study is truly a pragmatic study—it appears the term pragmatic is used more as a descriptor of the type of intervention rather than the actual trial design. The authors do not include any mention of PRECIS-2, the premiere tool available for designing trials with a more explanatory or more pragmatic attitude. To avoid misconceptions in the field, the authors are strongly encouraged to remove the term pragmatic throughout the manuscript (including the title), as it is relatively inaccurate and inconsistent with the more substantive conceptualization of the term pragmatic. In other words, using the term pragmatic to describe a trial done in the 'real-world' with less stringent inclusion/exclusion criteria and a use of a relatively low-intensity implementation strategy is a misnomer. Note that this is an extremely common use of the term, but it would be beneficial to the field overall if this misconception is not promulgated. For these reasons, the authors should remove this term from their manuscript unless they indeed planned the trial a priori to be more pragmatic across most—if not all—of the PRECIS-2 domains.

Response: Thank you for drawing our attention to this. We agree that the term has been used more as a descriptor of the type of intervention rather than the actual trial design. In response the term has now been removed throughout the document (title, abstract, pages 5, 6 and 18).

2. To avoid confusion and to be consistent with the field, the authors should remove the term 'implementation intervention' and replace or describe as implementation strategies. See Curran et al. (2012) for examples of interventions vs. implementation strategies, as well as articles by Powell and colleagues for more detailed descriptions of implementation strategies. The term 'intervention' should be reserved for approaches that target individual or patient-level health behaviors or outcomes; the audit and feedback approaches described in the manuscript should be labeled implementation strategies.
Response: Thank you for this comment. We agree and note that this has been addressed in response to related comments raised by reviewer 1. For text changes see response 5 to reviewer 1 above.

3. The authors should describe—in more detail than in the current version—exactly how CFIR informed the content of the implementation strategies.

Response: Thank you for this comment. In response we have revised text on page 9 describing the application of the CFIR and included an additional table summarising how the CFIR constructs were applied to inform the content of the implementation strategies. The table is now a new Table 1, to be inserted on page 9 and titled: Application of the Consolidated Framework for Implementation Research

The new text on page 9 reads:

“Formative work including consultations with local childcare services was conducted to identify relevant factors that may impede local implementation of the targeted policies and practices. Damschroder’s Consolidated Framework for Implementation Research (CFIR) was then used to help classify barriers and inform content to address them that could be delivered within an audit and facilitated feedback approach [35]. Damschroder’s Consolidated Framework for Implementation Research integrates 19 theoretical models and is composed of five major domains identified as influential in successful implementation: innovation characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation [35]. Table 1 provides a summary of the four targeted constructs and how these were applied.

4. Provide a citation or brief explanation for of a 20% difference between the two groups was used in the power analysis.

Response: Thank you for this comment. Given that a clinically significant effect size has not been established for implementation trials targeting service outcomes, the figure was included as it was deemed by the Population Health Unit (HNEPH) responsible for improving policy and practice implementation as meaningful from a public health service delivery perspective. To acknowledge this we have included additional text and references to the sample size calculation section on page 13/14 which reads:
A difference of 20% was deemed by the Population Health Unit (HNEPH) responsible for improving policy and practice implementation as meaningful from a public health service delivery perspective and similar to policy and practice changes observed in previous studies conducted by the research team in this setting [43, 44].

5. The CFIR model suggests that multi-component strategies are necessary, so why only use audit and feedback? Why did the authors decide to only use audit and feedback strategies if previous research has found that multi-component strategies are important (essential?) for increasing adoption of evidence-based practices?

Response: Thank you for this comment. Overviews of systematic reviews have found that multi-strategy implementation approaches are not more effective than single strategies [1]. Rather the effects of such strategies are likely to be based on how well they address the underlying impediments to change [1]. In this study, formative work and previous research identified that services had adequate resources [2], considered implementation of physical activity and nutrition practices as important [2], and routinely received training to support them to do so [3]. The strategy tested in this study was therefore selected as feedback is a recommended strategy [4] for influencing additional implementation factors such as beliefs about capabilities and motivation identified from previous research [5] and from formative evaluations. Examples include motivation and beliefs about capabilities. To acknowledge this we have included additional text in the introduction on page 5 which reads:

“Additional attractive features of audit and feedback are its capacity to be routinely delivered using modalities such as telephone that enable reach to large numbers of services at relatively low cost, and its ability to address identified implementation barriers including beliefs about capabilities and motivation [28].”

In regards to the CFIR, we applied this to inform the intervention content within the context of an audit and facilitated feedback approach. We also feel that the additional information regarding the application of the relevant constructs to this implementation strategy (as described in new table 1) provides a better indication of how the CFIR constructs were utilised (see response to reviewer 3 comment 3 above).
6. Why was the study conducted if they didn't achieve the target sample size? Why conduct a study if you are under-powered from the beginning?

Response: Thank you for this comment. This trial was conducted as part of government funded service delivery using routine data monitoring systems and is a reflection of the challenges faced when conducting trials in real-world circumstances at scale. On this basis we believe that this study still represents an important contribution to the limited literature regarding implementation of obesity prevention interventions in the childcare setting whilst also acknowledging that sample size was a potential limitation in regard to the trial outcomes (page 19).

7. If practices were excluded from the study because they were implementing many of the policies already (as stated on p. 19), why did both groups show relatively high rates of implementation at baseline? Shouldn't they have made the inclusion/exclusion criteria a bit more stringent to avoid ceiling effects at baseline, and thus limiting potential for improvement at follow-up? If the authors are only referring to two policies, as mentioned in the results section, perhaps the statement on ceiling effects at baseline could be softened.

Response: Thank you for drawing our attention to this. Given there are two targeted practices with relatively higher baseline implementation indicated in results we agree that the statement in relation to ceiling effects as written in the discussion is confusing and have decided to remove it.

[For reference these practices included: Service providing structured and specific learning experiences about healthy eating at least two times per week (intervention 83.9%, control 84.8%); and Service limiting use of small screen recreation by children aged 3-5 years to only educational purposes and for learning experiences (intervention 79.0%, control 82.6%).]

8. The selection of a 12-month follow-up time point should be justified. Why not 6-months and 12-months, which would allow for more sophisticated analyses (GEE) and potential assessment of sustainability? Data collection with CATI seems relatively easy; an explanation for why additional data points were collected would be beneficial.
Response: Thank you for this comment. This trial was conducted as part of government funded service delivery with baseline and follow-up data collection planned to align with 12 monthly routine data collection. In response we have added additional detail describing this context and explaining the choice of follow-up period. The additional sentence added to the outcomes section on page 11 reads:

“The interviews were conducted as part of government funded service delivery with baseline and follow-up data collection aligned with 12 monthly routine practice assessment.”

We have also acknowledged the single follow-up time point within the limitations section of the discussion. The additional sentence added to page 19 reads:

“Third, outcomes were assessed post-intervention at one time point only. Additional time points would allow for more sophisticated analyses and potential assessment of sustainability. “

9. Were there any policy changes outside the context of the trial that may have led to increases in the control group? Is there evidence that adoption of these or similar policies increase over time without any implementation strategy? A potential explanation for why the control group increased adoption of policies over time would be helpful.

Response: Thank you for this comment. One significant policy change acknowledged as a potential contributor to policy and practice implementation increases in the control group was the introduction of the National Quality Standards for the setting (including nutrition and physical activity elements). This, in addition to a number of other factors, is acknowledged in the discussion on page 18 via the following text:

“Additional factors may have also facilitated policy and practice implementation in the control group potentially reducing the likelihood of an intervention effect. These include the introduction of the National Quality Standards for the setting (including nutrition and physical activity elements) in the 12 months prior to the commencement of the trial and broad government support for implementation of policies and practices occurring state-wide.”
References:


